104TH CONGRESS
2D SESSION

H. R. 3959

To establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 1996

Mrs. JOHNSON of Connecticut introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Cancer Clinical Trial Program Coverage Act of 1996".

SEC. 2. MEDICARE CANCER PATIENT DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—Not later than January 1, 1997, the Secretary of Health and Human Services (in this Act referred to as the "Secretary") shall establish a demonstration project which provides for payment under the Medicare Program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) of routine patient care costs—

(1) which are provided to an individual diagnosed with cancer and enrolled in the Medicare Program under such title as part of the individual's participating in an approved clinical trial program; and

(2) which are not otherwise eligible for payment under such title for individuals who are entitled to benefits under such title.

(b) APPLICATION.—The beneficiary cost sharing provisions under the Medicare Program, such as deductibles, coinsurance, and copayment amounts, shall apply to any individual participating in a demonstration project conducted under this Act.

(c) APPROVED CLINICAL TRIAL PROGRAM.—For purposes of this Act, the term "approved clinical trial program" means a clinical trial program which is approved by—

(1) the National Institutes of Health;

(2) a National Institutes of Health cooperative group or a National Institutes of Health center;

(3) the Food and Drug Administration (in the form of an investigational new drug or device exemption);

(4) the Department of Veterans Affairs;

(5) the Department of Defense; or

(6) a qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(d) ROUTINE PATIENT CARE COSTS.—

(1) IN GENERAL.—For purposes of this Act, "routine patient care costs" shall include the costs associated with the provision of items and services that—

(A) would otherwise be covered under the Medicare Program if such items and services were not provided in connection with an approved clinical trial program; and

(B) are furnished according to the design of an approved clinical trial program.

(2) EXCLUSION.—For purposes of this Act, "routine patient care costs" shall not include the costs associated with the provision of—

(A) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

(B) any item or service supplied without charge by the sponsor of the approved clinical trial program.

SEC. 3. STUDY, REPORT, AND TERMINATION.

(A) STUDY.—The Secretary shall study the impact on the Medicare Program under title XVIII of the Social Security Act of covering routine patient care costs of individuals with a diagnosis of cancer and other diagnoses, who are entitled to benefits under such title and who are enrolled in an approved clinical trial program.

(b) REPORT TO CONGRESS.—Not later than January 1, 2001, the Secretary shall submit a report to Congress that contains a statement regarding—

(1) any incremental cost to the Medicare Program under title XVIII of the Social Security Act resulting from the provisions of this Act; and

(2) a projection of expenditures under the Medicare Program if coverage of routine patient care costs in an approved clinical trial program were extended to individuals entitled to benefits under the

Medicare Program who have a diagnosis other than cancer.

(c) TERMINATION.—The provisions of this Act shall not apply after June 30, 2001.

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